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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/502,698	02/11/2000	Shin-Ichi Funahashi	06501-056001	5541

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EXAMINER

MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 04/18/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/502,698

Applicant(s)
Funahashi et al.

Examiner
Prema Mertz

Art Unit
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 31, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3 and 6-37 is/are pending in the application.
- 4a) Of the above, claim(s) 6-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 35-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

1. The request filed on 1/31/03 in Paper No. 21 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/502,698 is acceptable and a CPA has been established. An action on the CPA follows.
2. Claims 3, 35-37 are under consideration. Claims 6-34 are drawn to non-elected claims.
3. Receipt of applicant's arguments filed in Paper No. 22 (1/31/03) is acknowledged.
4. Applicant's arguments filed in Paper No. 22 (1/31/03), have been fully considered but were non-persuasive. The issues remaining are stated below.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 101

6. Claims 1-5, 35-37 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

This rejection is maintained for reasons of record set forth at pages 2-5 of the previous Office action (Paper No. 11, 9/11/01) and at pages 2-7 of the previous Office action (Paper No. 14, 6/4/02).

Applicants argue that the identification of a protein as a member of the PDZ family is enough because it asserts a utility specific to the subject matter claimed. However, contrary to Applicants arguments, in the instant case, there is an asserted utility but no specific utility. Additionally, Applicants argue that the instant protein is a member of the class of beta-proteins

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and has specific utility as a PDZ domain polypeptide that interacts with PDZ binding transmembrane proteins which play a role in signal transduction, particularly cell proliferation, neural transmission, apoptosis and malignant conversion. However, the instant specification does not disclose any information regarding functional characteristics or the biological activity of the instantly claimed protein. While the specification on pages 19-26, describes many activities for the instant protein, such as the polypeptides being valuable targets for developing pharmaceuticals, there is no guidance given about which specific activity/activities the claimed polypeptide would be likely to have. The specification does not demonstrate that the claimed polypeptide actually displays any of these recited activities, i.e. cell proliferation, neural transmission, apoptosis and malignant conversion. In the absence of knowledge of the specific biological significance of the claimed protein, there is no immediately obvious patentable use for it. Since the instant specification does not disclose a "real world" use for protein, the claimed invention is incomplete and, therefore, does not meet the requirements of 35 USC § 101 as being useful.

The only disclosed function for the protein of the instant invention is that it is a member of the PDZ family of proteins (see page 3, lines 5-8). Applicant is only required to identify one substantial credible utility and the employment of this protein only as the subject of further research does not satisfy the utility requirement of 35 U.S.C. § 101 because the courts have interpreted this statute as requiring an invention to have "substantial utility" "where specific

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benefit exists in currently available form". The employment of a protein of the instant invention, as a marker for ovarian cancer is not a substantial or specific utility.

Applicants disclose in the specification that the claimed protein is a member of the PDZ family of proteins (page 3, lines 5-8). The state of the art is such that functional information can be automatically derived from structural information only to a limited extent, (see Sklonick et al, Nature Biotechnology, Vol.18, No.3, pages 283-287, especially page 286, middle of column 1). Sklonick et al also state that knowledge of the overall structure or domain family is still not enough to confidently assign function to a protein. Therefore, there is little doubt that, after further characterization, the protein is found to be member of the PDZ family, the claimed protein would have a specific, substantial and credible utility. However, further characterization is part of the invention and until it had been undertaken, the claimed invention is not supported by a specific asserted utility or a well established utility. The claimed invention is directed to a polypeptide of as yet undetermined function or biological significance. Thus, since there is no specific biological activity disclosed for the claimed protein, the claimed invention is not supported by either a specific and substantially asserted utility or a well established utility.

Claims 3, 35-37 are also rejected under 35 U.S.C. 112, first paragraph.

This rejection is maintained for reasons of record set forth at pages 2-5 of the previous Office action (Paper No. 11, 9/11/01) and at pages 2-7 of the previous Office action (Paper No. 14, 6/4/02).

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Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The instant specification does not disclose a biological activity for the claimed protein, therefore, there is no specific and substantial asserted utility or well established for the claimed protein. The fact that the protein is a member of the PDZ family is not sufficient to establish a specific and substantially asserted utility or a well established utility for it.

Conclusion

The claims are free of the prior art.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 305-3014 or (703) 308-4242.

Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Prema Mertz
Prema Mertz Ph.D.
Primary Examiner
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March 5, 2003